UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ELIZABETH A. HOLMES and RAMESH "SUNNY" BALWANI,

Defendants.

Case No. 5:18-cr-00258-EJD-1

ORDER RE PRODUCTION OF DOCUMENTS BY FDA AND CMS

Re: Dkt. No. 67

Before the court is Defendant Elizabeth Holmes's Motion to Compel Production of Rule 16 Discovery and *Brady* Materials. Dkt. No. 67. Defendant Ramesh "Sunny" Balwani joined the Motion. Dkt. No. 68. The Court has reviewed the parties' papers, twice heard from the parties, and considered FDA and CMS's representations to the Court. The Court's directions to FDA and CMS are laid out below. This order addresses only the production of documents by FDA and CMS; the issues relating to the agent notes will be addressed separately.

To prepare their defenses, Defendants seek six categories of documents that are in the possession of FDA and/or CMS. Those categories are:

> Category 1: Any and all correspondence or communications regarding Theranos between the government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same.
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> Category 2: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos.
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> Category 3: Any and all correspondence or communications

> regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or interagency correspondence) regarding same.
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> Category 4: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology.
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> Category 5: Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same.
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> Category 6: Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

Mot. at 1-2.[1] Defendants moved, pursuant to Federal Rule of Criminal Procedure 16 and *Brady v. Maryland*, 373 U.S. 83 (1963), to compel the Prosecution to produce all documents responsive to these categories. The Prosecution opposes the Motion, in part, on the grounds that the sought-after documents are not in its possession. Dkt. No. 79.

With its opposition, the Prosecution filed a letter from FDA Senior Counsel Marci B. Norton dated June 7, 2019 ("June FDA Letter") (Dkt. No. 79-4), and another letter from CMS Director of the Division of Clinical Laboratory Improvement and Quality Karen W. Dyer dated June 10, 2019 ("June CMS Letter) (Dkt. No. 79-5). While the letters are addressed to the Prosecution, the Court understands these letters to be the agencies' representations to the Court with the Prosecution acting as the conduit. In the June FDA Letter, FDA represented that it had already been served a subpoena for documents in the Securities and Exchange Commission's civil case against Balwani (the "Civil Case"). June FDA Letter at 2. It explained that Defendants' requests comprise a "subset" of the documents subpoenaed by Balwani. *Id.* FDA agreed to

[1] "[T]he government" is defined as FDA and CMS. *See* Mot at 1 n.1. This Order refers to the prosecution team from the U.S. Attorney's Office as "the Prosecution" instead of "the government" to avoid confusion.

produce the documents responsive to Defendants' requests that it finds while responding to the subpoena but subject to certain limitations. *Id.* Without providing a timeline, the FDA warned that the production could take a "significant" amount of time. *Id.* at 4. CMS represented that it agreed to produce responsive documents and discussed each category of requests. June CMS Letter. CMS noted that it was also preparing a production in the Civil Case. *Id.* at 2.[2] CMS did not provide any sort of anticipated timeline for its production. Both agencies raised concerns related to certain types of confidential information that would appear in the documents.

On June 28, 2019, the Court held a hearing on the Motion. The parties indicated that they would meet and confer on a stipulated protective order to address the agencies' concerns, and to obtain a waiver from the Theranos Assignee. That day, the Court issued an order directing FDA and CMS to provide the parties with specific information on the documents that they agreed to produce. Dkt. No. 84. The Court did not issue a final order on the Motion and continued the hearing until July 17, 2019. *Id.*

On July 15, 2019, the parties filed a Joint Status Memorandum to update the court on the status of the production. Dkt. No. 89. The Prosecution represented that it had communicated with FDA and CMS to resolve their concerns. *Id.* at 2. The Prosecution prepared the stipulated protective order, which the Court has signed (Dkt. No. 90), and obtained a waiver from the Theranos Assignee authorizing the agencies to produce Theranos's confidential documents to Defendants. Joint Status Mem. at 2.

FDA and CMS also submitted letters updating the Court and the parties on the status of their productions. FDA's letter is signed by Norton and dated July 9, 2019 ("July 9 FDA Letter"). Dkt. No. 89-2. CMS's letter is signed by Dyer and dated July 12, 2019 ("July 12 CMS Letter"). Dkt. No. 89-3. FDA stated that it provided its letter "pursuant" to the Court's Order, and CMS stated that its letter "respond[ed]" to the Order. July 9 FDA Letter at 1; July 12 CMS Letter at 1. Both agencies stated that they will search for documents responsive to Defendants' requests, that

[2] CMS did not paginate this letter. This pincite goes to the ECF page number.

they would not withhold documents regarding Theranos based on the deliberative process privilege, that they would begin producing documents once the waiver is provided and the protective order is entered, and that they would not redact or withhold personally-identifying information from the documents. July 9 FDA Letter; July 12 CMS Letter; Joint Status Mem. at 3-4. FDA represented that it would not withhold documents based on relevance objections, but it did list six limitations that it would apply. July 9 FDA Letter at 2-4. Limitation Number 4 states that FDA will not produce documents "available from public media or similar organizations" that do not also "include commentary by FDA employees." *Id.* at 3. FDA represented that its production would take six months. *Id.* CMS provided anticipated dates of production for some subsets of documents, but also stated that it could not provide a clear timeline for the production of internal, Theranos-related email. July 12 CMS Letter at 4. Defendants objected to FDA's anticipated six-month timeline and CMS's failure to provide a clear timeline. Joint Status Mem. at 6-7. The Prosecution agreed that FDA's timeline was too long. *Id.* at 6.

After the parties filed the Joint Status Memorandum, FDA and CMS again submitted letters. In FDA's letter, signed by Norton and dated July 16, 2019, it further explained its bases for the six-month estimate ("July 16 FDA Letter"). Dkt. No. 105 at 1. CMS's letter, signed by Dyer and dated July 17, 2019, clarified that while CMS would not withhold documents related to Theranos based on the deliberative process privilege, it would not waive that privilege as to matters not related to Theranos ("July 17 CMS Letter"). Dkt. No. 106. The Court then heard from the parties at the continued hearing on July 17, 2019.

Based on the parties' representations and the representations of FDA and CMS, the Court believes that the most effective and timely manner for Defendants to receive the documents is to continue with the current process by which the Prosecution works with FDA and CMS to produce the documents. FDA and CMS have represented to the Court that they will produce all documents responsive to the Defendants six requests. July 16 FDA Letter at 2 ("FDA is, and has been, working diligently to collect, process, review, and ultimately produce all documents responsive to all six categories requested by the parties."); July 12 CMS Letter at 1 ("CMS agreed to provide

documents in the agency's possession between September 1, 2013 and December 3, 2016 that are responsive to the six categories of documents requested and that are not protected by the attorney-client or work product privileges."). The Court is cognizant of the agencies' cooperation and takes them at their word that they will diligently search for and produce the responsive documents.

However, the Court—and both parties—find that FDA's anticipated six-month schedule for production is unacceptable. The Court finds CMS's failure to provide an anticipated timeline to be concerning. The Court further finds that it will benefit FDA, CMS, and the parties to clarify the categories of documents at issue. Accordingly, the Court directs FDA and CMS as follows:

1. FDA and CMS are to search for and produce to the Prosecution all documents responsive to the six categories of documents described above, *i.e.*, the six categories stated in Defendants' Motion. Mot. at 1-2.
2. FDA and CMS shall complete their productions of documents no later than October 2, 2019.
3. FDA and CMS shall advise the Prosecution no later September 23, 2019 whether they anticipate completing their productions by the deadline. They shall advise the Prosecution of how many documents they anticipate producing by the deadline, the anticipated total number of documents in their final productions, and—if they do not anticipate completing their productions—the reasons why they cannot complete it and how much additional time they would need. The Prosecution shall share this information with Defendants without delay.
4. From the date of this order until September 23, 2019, FDA and CMS shall keep the Prosecution reasonably apprised of the status of their productions. The Prosecution shall share such information with Defendants.
5. To the extent that FDA does not produce documents "available from public media or similar organizations" that do not also "include commentary by FDA employees," FDA shall maintain and produce a log of all such documents that are withheld.

The hearing on Defendants' Motion to Compel is continued until 10:00 a.m. on October 2, 2019. The parties shall file a joint status report concerning FDA and CMS's productions no later than 5:00 p.m. on September 30, 2019. The Court, again, defers ruling on the Motion.

IT IS SO ORDERED.

Dated: July 19, 2019

EDWARD J. DAVILA
United States District Judge